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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,328	09/21/2000	Gary W. Pace	121-112	8438

7590

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/667,328

Applicant(s)

PACE ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5. 6) ☐ Other: _____

DETAILED ACTION

Applicant's election without traverse of ethyl oleate as the non-aqueous medium, phospholipid as the specific surfactant system, and ethanol as the specific hydrophilic substance in Paper No. 8 is acknowledged. However, upon consideration, the species election requirement is withdrawn. **Claims 16-38 are included in the prosecution of this application.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 30 recitation of "non-aqueous hydrophobic liquid" and its intended meaning is unclear. Clarification is requested because claims 17 and 31 recite several compounds which are hydrophilic such as monohydric alcohols, dihydric alcohols, polyhydric alcohols, and glycerin, as non-aqueous hydrophobic liquids. The same components are recited as hydrophilic components in claims 20 and 34. The distinction between "hydrophobic liquid" and "surfactants" in claim 16 is unclear for the following reason: claims 18 and 32 recite monoglycerides, triacetin, diacetin, monoacetin as surfactants; however the same components are recited in claim 17 and 31 as hydrophobic liquids. Furthermore, claim 18 and 32 recite several celluloses as

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surfactants; it is unclear as to how these components are considered as surfactants. In view of this confusion, it is essential that applicant define the generic terms in claims 16 and 30 in terms of specific compounds.

In claims 17 and 31, it is unclear as to what applicant intends to convey by 'fish oil free fatty acid'. Does it mean that the fatty acids are prepared from fish oil? What is the distinction between an alkanol, monohydric alcohol and dihydric alcohol? What is 'perflubron'?

What is "a protein used in the treatment of diabetes" in claims 22 and 35? Does applicant mean insulin? What is a derivative of insulin as recited in claims 23 and 36?

The distinction between 'water containing soluble agents for lyoprotection' and 'water containing pharmaceutically acceptable lyoprotectants' and similar expressions used for cryoprotectants and polyols in claims 25 and 37 is unclear.

What is being claimed through claims 26 and 38? This claim recites several body fluids including urine, vaginal fluids, and pancreatic fluids. According to parent claim the fluid is added to the composition so that the composition self-disperses. The purpose of this is unclear. How can one collect pancreatic fluid for example and then disperse the composition to form a suspension and for what purpose?

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

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to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 17, 18, 20, 25, 31, 32, 34, and 27 recite broad recitation followed by a narrow limitation. For example, in claim 17, broad limitation of "an oil derived from animal origin" followed "fish oil" which is the narrow limitation. For example, in claim 18 the broad limitation "cellulose derivatives, and the claim also recites "methylcellulose, hydroxycellulose" which is the narrower statement of the range/limitation.

The term "for use" in claim 24 is a relative term which renders the claim indefinite. The term "for use" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The examiner suggests restructuring the claim to read, "The composition of claim 16 sustained or controlled delivery in a sustained or controlled delivery formulation..."

The examiner suggests revision of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16-18, 20-32, and 34-38 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/29300.

WO 99/29300 teaches a self-emulsifying composition containing a hydrophobic drug (fenofibrate), a hydrophobic liquid, a surfactant, and a hydrophilic component. The particle sizes are 10nm to 10 microns. (Note examples) The composition is in the form of hard or soft capsules and tablets with coating (pg. 9).

Claims 16-18, 20-32, and 34-38 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/29316.

WO 99/29316 teaches a self-emulsifying composition containing a hydrophobic drug (cyclosporin), a hydrophobic liquid, a surfactant, and a hydrophilic component. The particle sizes are 10nm to 10 microns. (Note examples) The composition is in the form of hard or soft capsules (claim 38).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al (5656289).

Cho et al teaches a pharmaceutical composition containing insulin, oleic acid, ethanol, and lecithin (Note example 1). Cho et al teach coating capsules for administration and particle size is 1.5-2 mm (Note example 13 and 16).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-27 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al (5660858) in view Haynes (5091187).

Parikh et al teach a cyclosporin emulsion containing egg phospholipid, linoleic acid, triglycerides, glycerol (Note examples). The formulation is in an injectable formulation (col. 1, lines 10-15). Parikh et al teach the particle sizes to be less than 1 micron (col. 3, lines 25-36).

Parikh et al do not teach the instant particle size.

Haynes teaches phospholipid-coated injectable formulation of water-insoluble drugs. Haynes teaches a hydrophobic phase, a hydrophilic phase, and surfactant system (Note examples). Haynes teaches the size of the particles for an injectable formula must be 10 microns or less to prevent the blockage of capillaries, etc. If the particle size is above 10 microns, then the formulation must be in oral dosing form (col.2, lines 9-21).

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Parikh et al and Haynes since both teach injectable formulas. One would be motivated to do so since Haynes teaches that an

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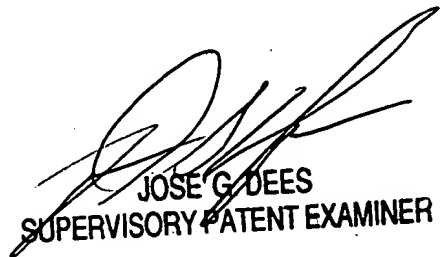
injectable formulation can have a maximum particle range of 10 microns; thus the particle size of Parikh et al can be manipulated within the range for an injectable formula.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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